

**COMPARATIVE EVALUATION OF
ETHACRIDINE-CARBOPROST (PGF_{2α}) COMBINATION
WITH ETHACRIDINE - SYNTOCINON FOR
MID - TRIMESTER ABORTIONS**

**THESIS
FOR
MASTER OF SURGERY
(OBSTETRICS AND GYNAECOLOGY)**



**BUNDELKHAND UNIVERSITY
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CERTIFICATE

This is to certify that the work enclosed in the thesis entitled "A COMPARATIVE EVALUATION OF ETHACRIDINE-CARBOPROST ($\text{PGF}_{2\alpha}$) COMBINATION WITH ETHACRIDINE-SYNTOCINON FOR MID-TRIMESTER ABORTIONS" is the original work carried out by DR. SHWETA BANSAL under my supervision and guidance in the Department of Obstetrics and Gynaecology, M.L.B. Medical College, Jhansi.

I have checked from time to time her method of work and the results obtained. The candidate has fulfilled the necessary stay in the department as per university regulations.

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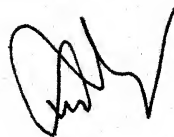
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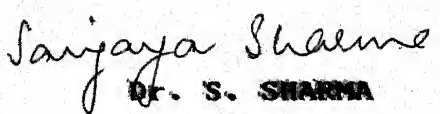
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This work fulfils the basic ordinances governing the submission of thesis laid down by Bundelkhand University, Jhansi.


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**DEDICATED TO
MY BELOVED DAUGHTER
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Date 31.8.94.

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Introduction

INTRODUCTION

From time immemorial, abortion have been practised in the world with or without legal and social sanctions. Legal abortion has earned much popularity in the last decade because of its greater safety and large impact on population control. The historical evidence is also strong that rapid fertility decline is unlikely without some recourse to abortion (Corvalan, 1979). Thus, more and more countries in the world are liberalising their abortion laws.

In India, since the enactment of the Medical Termination of Pregnancy (MTP) Act of 1972, several thousands of abortions are performed every month. The demand for abortion has greatly increased since then. Various methods are in practice depending on the duration of pregnancy.

Induction of abortion during the second trimester of pregnancy has always been problematic. The second trimester abortions constitute about 15% of the total abortions reported in the country. Due to the detection of prenatal foetal sex anomalies in second trimester, the incidence of termination of pregnancy during this period has increased considerably.

A large number of techniques have been evaluated for second trimester MTP—a fact which testifies that all the present day methods have some short coming and no single technique is absolutely safe and effective.

The method most frequently employed along with the minor section has been the induction of abortion by saline or ethacridine solution. Induction of early second trimester abortion by the intra and extra amniotic administration of hypertonic saline has been utilised extensively in the Canadian countries, but the method is associated with the risk of intravascular leakage of saline in substantial amounts, (Bengtsson; Amris).

An alternative is ethacridine; a yellow acridine derivative (6, 9-diamino-2-oxyethyl acridine-lactate dissolved in sterile water) with antiseptic and oxytocic properties (Lewis; Sepekas N.). It can also be administered extra-amniotically as a 0.1% solution. This method of abortion, in combination with the rubber catheter has been used with success by Japanese Obstetricians (Manabe, Y.). The 0.1% ethacridine solution has the advantage of being harmless even in the event of intravascular leakage. It is a

well established agent and has an excellent record of safety over many years of clinical experience.

On the other hand, this method has the disadvantage that it must be combined with other agents-usually an indwelling catheter or concurrent oxytocin administration in order to be effective within a reasonable period of time. Significant uterine contractility usually does not occur until 10-12 hours following ethacridine-instillation. It has the drawback of higher failure rate and longer induction-abortion interval compared to other agents like hypertonic saline or prostaglandins.

In India, the available alternative for termination of mid-trimester pregnancy- are hysterotomy or hypertonic saline. Hysterotomy is a major surgical procedure and hypertonic saline has the risk of coagulation failure. Therefore, it is imperative to evolve safe and effective methods for this group.

Encouraged by the results of the WHO Task Force on prostaglandins and reports from various parts of the world (Anderson G.C.; Brenner, W.E.); the Indian Council of Medical Research initiated a trial with Prostaglandin F_{2α} (PGF_{2α}) and 15-Me-analogue of PGF_{2α} for termination of mid-trimester of pregnancy. Independent studies have shown that potential value of

PG of the E and F α series both as parturigenic agents (Embrey; 1969, 1970; Beazley et al. 1970; Karim et al., 1970; Roth-Brandel and Adams, 1970;) and as abortifacients (Embrey 1970b; Karim and Filishie 1970a, 1970b).

Prostaglandins (the most potent oxytocic agent known) are very effective but associated with a number of disadvantages including the complications; the expense and the non-availability.

It is now generally accepted that combination methods, using prostaglandins in conjunction with other agents, are the method of choice for medically terminating second trimester pregnancies.

A popular method for terminating second trimester pregnancy is the combination of extra-amniotic ~~ethacridine~~ lactate plus prostaglandin. However, though this combination method has been recommended for second trimester abortion for over 10 years, a number of details to optimize the technique have yet to be studied.

The present study was undertaken to explore the clinical efficacy of combining the immediate effect of a single extra amniotic injection of PGF α with more slowly developing but longer lasting stimulatory effect of ethacridine i.e. the aim was

to combine the safety of ethacridine with efficacy of prostaglandins. The prostaglandin $15(s)$, 15-methylyl $\text{PGF}_{2\alpha}$ was administered extra-amniotically to reduce systemic side effects and the inconvenience of intramuscular route.

The induction of early second trimester abortion by the extra amniotic instillation of a single dose of prostaglandin ($\text{PGF}_{2\alpha}$) with a solution of 0.1% ethacridine, seems to be simple, efficacious and harmless procedure. This modification of extra amniotic abortion method combines the immediate uterotonic effect of prostaglandin with the delayed oxytocic response to ethacridine. It is postulated that a stimulation of increased $\text{PGF}_{2\alpha}$ release from the decidua may be the final mechanism of action for ethacridine.

This study was a comparative evaluation of use of ethacridine- $\text{PGF}_{2\alpha}$ combination and ethacridine-syntocinon for mid-trimester abortion and was done with the following aims and objectives :

- I. To find out the safe, simple and effective method for mid-trimester termination of pregnancy by using ethacridine lactate extra-amniotically followed by single injection of Carboprost ($\text{PGF}_{2\alpha}$) extra-amniotically 6 hours later in one group and oxytocin-augmentation in the other group.
- II. To note the overall induction-abortion interval and compare the results in both the groups.
- III. To evaluate the safety of both the methods as regards the complications like incomplete abortion; pain, post-abortal bleeding and failure rates.
- IV. To observe the overall success rate in both the groups with regards to induction-delivery interval, cost effectiveness, side effects and complications.
- V. To combine the safety of ethacridine with the efficacy of prostaglandins for mid-trimester abortion.

Review of Literature

REVIEW OF LITERATURE

The controversy on the issue of induced abortions is well recognised. In recent years, it has reached critical dimensions. It is felt that it should be the right of each woman to take a decision on her pregnancy, based upon correct information.

Abortion has earned much popularity in the last decade because of its greater safety and large impact on population control. The world-wide trend towards liberalisation of abortion laws has continued in the last four years, thus bringing changes in Canada, Czechoslovakia, Hungary, The Soviet Union and Vietnam. Forty per cent of the world's people now live in countries where induced abortion is permitted on request and twenty five per cent in countries where it is allowed only if the women's life is in danger (Hanshaw, 1990).

PROBLEM STATEMENT

(a) WORLD : The number of pregnancies terminated yearly by induced abortions throughout the world is not definitely known because of inadequate data, under-registration of abortions and generally unreliable estimates of illegal abortions. It is estimated that 40-60 million abortions are performed in the world each year including 33 million legal procedures. This implies a

world-wide abortion rate of 37-55 per 1,000 women aged 15-44 years and a ratio of 24-32 abortions per 100 known pregnancies (Tietze and Henshaw, 1986).

(b) INDIA : Since legalisation of abortion in India, deliberate induction of abortion by a registered medical practitioner in the interest of mother's health and life is protected under the MTP Act 1971-75. In India, 518,600 pregnancies have been terminated legally in 1983-84, accounting for an abortion rate of 3.3 and abortion ratio of about 2 : 1. But, illegally induced abortions are estimated to have numbered 4-6 millions giving an abortion rate of 36-55 and an abortion ratio of 13-20 per 100 estimated pregnancies per year (Chaudhuri, 1988). Since the inception of the programme in India, in April 1972, over 6.38 million terminations were effected up to March 1989 under the MTP Act (Ministry of Health and Family Welfare, Govt. of India, 1990).

As a result of increased awareness created by the implementation of the MTP Act in India, more and more women are seeking legal abortions.

The use of pharmacological agents for the termination of early pregnancy is preferred over any surgical procedure due to

risks involved in instrumental evacuation. The ideal drug for this purpose should be safe, highly effective and easy to administer. Prostaglandins can be used to terminate pregnancies at any stage of gestation. However, when they are used to terminate pregnancies between 7-12 weeks; the induction-abortion time is significantly prolonged and the doses required produce unacceptable side effects.

During the second trimester between 13-20 weeks pregnancy when the foetus develops rapidly, the uterus is generally quiescent and unresponsive. At this stage, abortion is physically and psychologically more traumatic than the termination of early pregnancy or menstrual induction.

Different methods have been used to provoke abortion since time immemorial :

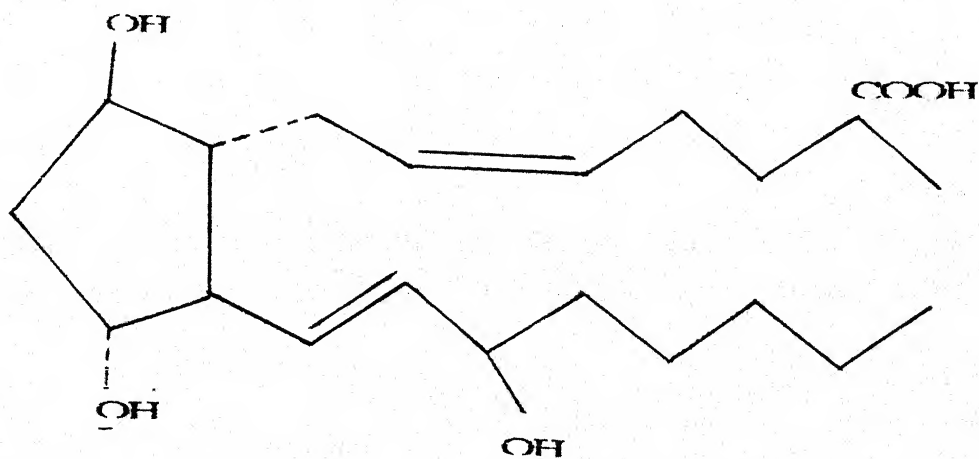
- (i) extra-ovular metrecrurysis.
- (ii) introduction of laminaria bougres.
- (iii) extra-ovular instillation of hypertonic saline, ethacridine lactate alone or in combination with syntocinon (Cohen, 1846).
- (iv) Prostaglandins (PGE_2 and $\text{PGF}_{2\alpha}$) and their synthetic analogues using intravenous, extra-amniotic, intra-amniotic or intra-vaginal routes of administration.

Continuous intravenous infusion of prostaglandin for termination of pregnancy was first successfully tried by Karim and Filshie (1970). Following this, several authors have reported a success rate ranging from 60-93%. Disadvantages of this route has been the high incidence of nausea, vomiting, diarrhoea and phlebitis at the site of infection. More recently, however, considerable interest has been directed towards other routes of administration.

Since the first systemic study of the prostaglandins by Kurzork and Lieb in 1930, many stimulating researches are being done on prostaglandins all round the world. Prostaglandins have revolutionised the management of pregnancy termination. They are considered to be the method of choice for second trimester abortions. They appear to have high efficacy and less side effects. The efficacy can be further enhanced and side effects further reduced when prostaglandins are administered in combination with some other method.

PROSTAGLANDINS

Term was coined by Von Euler (1935). Prostaglandins are naturally occurring substances of family of polyunsaturated 20 carbon fatty acids containing a cyclopentane ring and two



PGF₂α

aliphatic side chains. Chemically derivative of hypothetical prostanoic acid.

Prostaglandins are divided into groups A, B, C, D, E, F, G, H and I which are subdivided according to degrees of unsaturation of side chains and a suffix denoting the number of double bond (e.g. PGE_1 , PGE_2 , PGE_3). When stereoisomerism exists its nature is shown by additional subscripts alpha or beta ($\text{PGF}_{2\alpha}$ and $\text{PGF}_{2\beta}$). Only alpha isomer occur naturally.

BIOSYNTHESIS

In the body prostaglandins are derived from ercose (tri/litre/pento) enoic acids. Thus called eicosonoids. In human tissue, the fatty acids released from membrane lipids in largest quantity is 5, 8, 11, 14 eicosa tetraenoic acid (arachidonic acid). During prostaglandins synthesis, two of the four double bonds of arachidonic acid get saturated in process of cyclization, leaving two double bonds inside chain. Thus subscript 2 prostaglandins are most important in man e.g. PGE_2 , $\text{PGF}_{2\alpha}$, TxA_2 and PGI_2 .

Eicosonoids are most universally distributed autocoid in the body. Practically every cell and tissue is capable of synthesizing one or more types of prostaglandins. Endogenous

prostaglandins are known to be involved in regulation of female reproductive processes. Pickles and co-workers have identified the presence of prostaglandins in menstrual fluid, endometrium and in blood during menses (Elington et al. 1963; Pickles et al. 1965, 1967) while Karim, Devlin and Hiller identified the presence of E and F prostaglandins in the umbilical cord, amniotic fluid, decidua and in venous blood during spontaneous labour and abortion (Karim, 1966, 1967, 1968; Karim and Devlin, 1967; Karim and Hiller, 1970).

Arachidonic acid is a typical polyunsaturated fatty acid present in cells in esterified form, hence the liberation of glycerophospholipids of arachidonic acid is a key event in biosynthesis of prostaglandins and is thought to be the rate limiting step in this process (Samuelsson, 1978).

DEGRADATION

First step in prostaglandins metabolism - These are catalysed by 15 hydroxy prostaglandins dehydrogenase (PGDH) into biologically inactive 15 ketoderivatives, which are rapidly converted to the 13, 14 dehydroxy-15-keto derivatives the major circulating forms (Vonkeman et al. 1969).

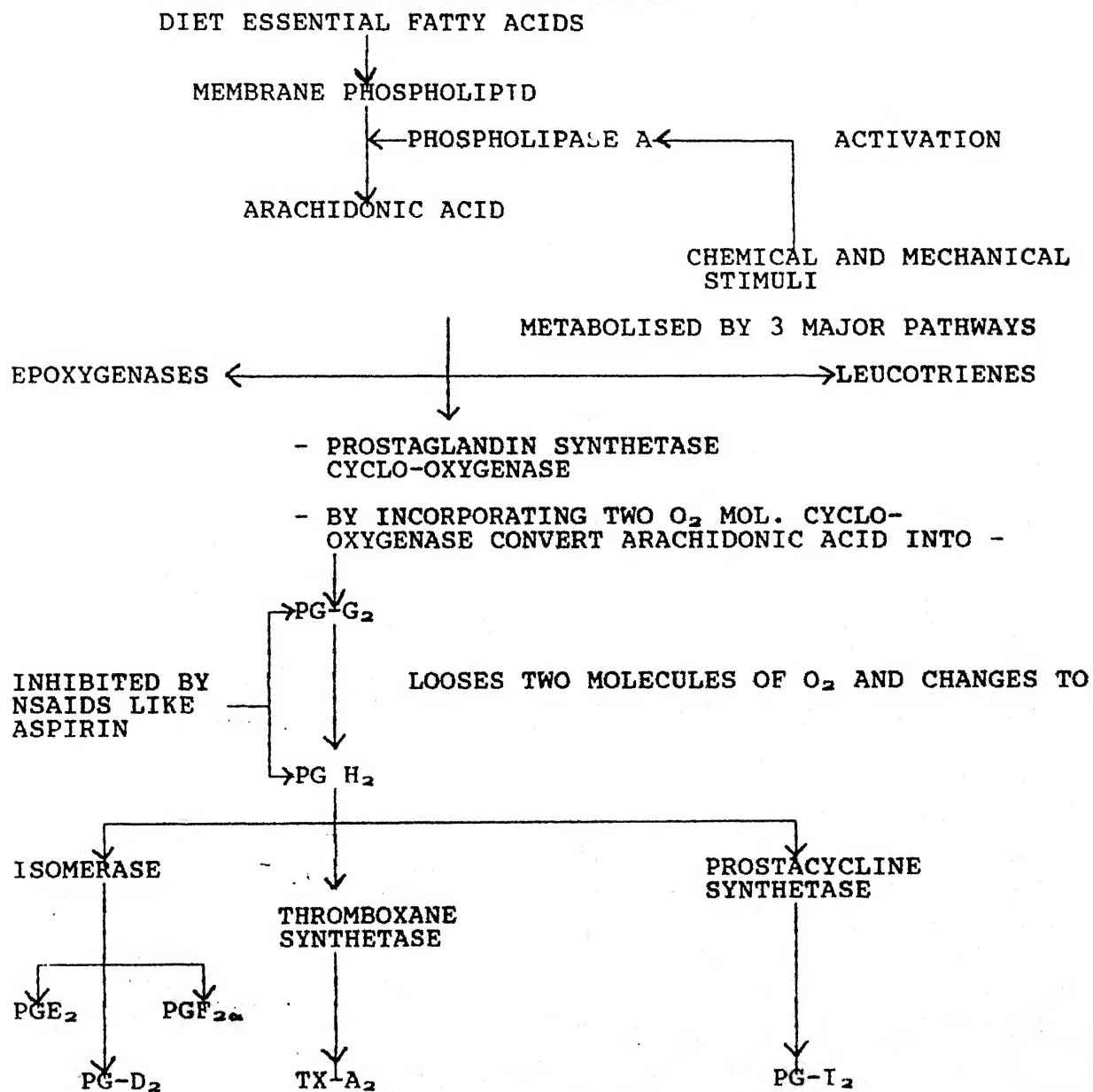
Degradation occurs rapidly in most tissues but fastest in the lungs. Plasma half life in few seconds to few minutes (Sameulsson, 1978). Elimination of biologically active prostaglandins is compared by beta and omega oxidations. The products formed are excreted in urine.

Pharmacologically to make the compound stable for therapeutic purposes such as induction of abortion, the 15-OH group of $\text{PGF}_{2\alpha}$ is replaced by 15- CH_3 group; and this compound 15-methyl- $\text{PGF}_{2\alpha}$, hence is not metabolised by 15-hydroxy prostaglandins dehydrogenase.

DISTRIBUTION OF PROSTAGLANDINS IN HUMAN REPRODUCTIVE ORGANS AND FLUID

Recent and more definite studies have shown that the distribution of prostaglandins is not restricted to the male accessory glands (prostate) or their secretions as reported earlier but prostaglandins have ubiquitous distribution in the female reproductive organs and fluids also. With increasing research, evidence has accumulated that prostaglandins are active throughout the reproductive system.

PROSTAGLANDINS SYNTHESIS IN THE BODY



By the late 1970s prostaglandins were known to be involved in hypothalamic and pituitary hormone releases, ovulation, development of corpus luteum, uterine contractions in labour and spontaneous abortions, ejaculation and sperm transport.

The types of prostaglandins in relation to the source as found by various workers are given in Table I.

Table I
TYPES OF PROSTAGLANDINS IN RELATION TO SOURCE

Source	Types of PGs	Investigators
Female Reproductive Tissues		
■ Maternal blood during preg; labour and spontaneous abortion	E_2 , $F_{2\alpha}$	Karim, 1968; Karim & Hiller, 1970 Brummer, 1972
■ Amniotic fluid in gestation and labour	$PGF_{2\alpha}$, $PGF_{1\alpha}$ PGF_2 , PGE_1	Karim and Devlin, 1967
■ Umbilical and placental blood vessels	PGE , PGF	Karim, 1967a
■ Fallopian tube	$PGF_{2\alpha}$	Ogra et al. 1974
■ Menstrual blood and endometrium	PGF_2 , PGF_2	Pickles and Hall, 1963; Downie et al 1974.
Male Reproductive Tissues		
■ Seminal fluid	E_1 , E_2 , E_3 , F_1 A_1 , A_2 , E_1 , E_2 19-hydroxy E_1 , E_2	Hamberg & Samuelsson, 1966; Bygdeman et al. 1970, Taylor & Kelly, 1974.

MECHANISM OF ACTION ON UTERINE MUSCLE

Exact mechanism is not clear. Different workers are of the views :

(1) Act by Calcium Displacement Mechanism :

- Prostaglandins interact with specific receptors localized in plasma membrane cells. In uterine muscle, the prostaglandin bind to the E_2 adrenergic receptors.
- PGE and PGF inhibit action of adenylate cyclase and decrease cyclic AMP, which in turn increase intra-cellular ionic calcium to actomyosin complex and in this way triggers myometrial contraction (Mary E. Cursten, 1972).

(2) Prostaglandins act indirectly through the release of oxytocin. Gillespie et al. (1972) have shown an increase of oxytocin level in prostaglandin induced abortions.

(3) According to Csapo and Pulkkinen, it is the reduction in progesterone supply due to constriction of uterine and placental blood vessels, thus making the myometrium receptive to prostaglandins (Csapo and Pulkkinen, 1979).

(4) Prostaglandins appear to induce abortion primarily through uterine contractions. These are probably stimulated both directly by the exogenous prostaglandins and indirectly by

enhanced release of endogenous prostaglandin. There is an increase in uterine muscle tone, followed gradually by regular contractions which physically dislodges the conceptus from the uterine wall.

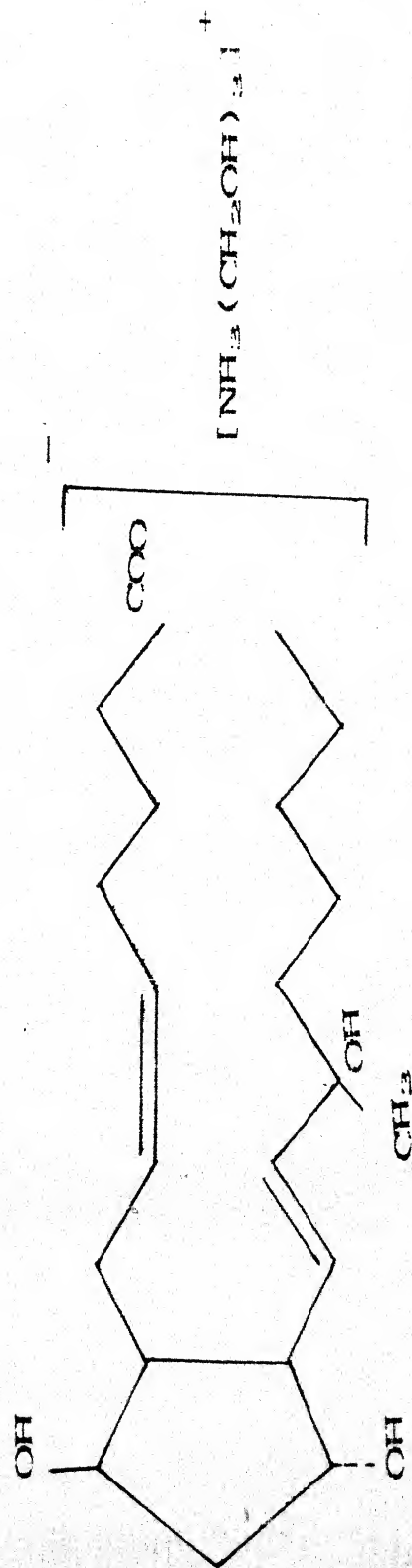
- (5) Prostaglandins are also involved in leuteolysis and inhibit the ability of corpus luteum to secrete the female hormone progesterone which is necessary for maintenance of pregnancy, thus causing abortion.

PROSTODIN

Prostodin is a synthetic analogue of naturally occurring prostaglandin $F_{2\alpha}$. Chemically it is tromethamine salt of 15(S)-15methyl $PGF_{2\alpha}$. The generic name is carboprost tromethamine.

The process of abortion by use of PGs is similar to labour at term. There is a latent phase during which the cervix dilates, softens and effaces to facilitate the passage of products of conception. This is followed by an active phase during which the products are expelled through the dilated cervical canal.

The primigravidae take 3-5 hours longer for expulsion. This is mainly due to longer latent phase-analogous to labour. Adequate uterine contraction (3-5 per 10 min.) with the tone returning to baseline is necessary for expulsion of products of



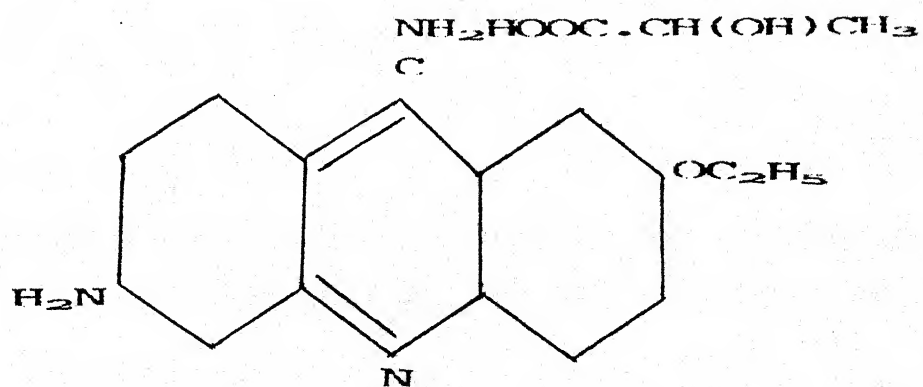
15(S)-15 METHYL PGF_{2α} (TROMETHAMINE SALT)

conception. On the other hand, contractions superimposed with high basal tone may lead to rupture of uterus, especially in absence of cervical dilatation. The incidence of incomplete abortion is higher during early second trimester than during late second trimester.

CONTRA-INDICATION FOR USE OF PROSTODIN

Prostodin is contra-indicated in the patients with following medical conditions:

- (a) Hypersensitive to prostodin
- (b) Asthma, allergic bronchitis
- (c) Epilepsy
- (d) Renal impairment
- (e) Cardiovascular diseases
- (f) Hepatic diseases
- (g) Grand multipara
- (i) Scarred-uterus-previous hysterotomy/cesarean section
- (i) Other relative contra-indications include large uterine myomata, major congenital anomalies of the uterus, failed saline inductions and purulent cervicitis or vaginitis.



ETHACRIDINE LACTATE

PHARMACOLOGY OF ETHACRIDINE LACTATE

Ethacridine lactate also known as "Acerenol lactate", "Lacto-actridine", "Aethacridinum-Lacticum", "Rivanolum" is 6-9, diamino, 2-oxyethyl-acridine lactate with a chemical composition of $C_{15}H_{15}N_3OC_3H_6O_3H_2ONH_2HOOC-CH(OH)CH_3$ in the following configuration

It is a yellow dye with antiseptic action. In 0.05 to 0.2% solution, it has been widely used as an antiseptic agent for skin and mucous membrane, 0.1% Rivanol, injection intravenously was found to be quite safe and was used in this concentration for many infectious diseases. It has been also used internally as urinary tract disinfectant. Absorption or intravasation of the drug is without any danger.

MODE OF ACTION

The oxytocic effect of Rivanol and other basic dyes in human uterine muscle is well documented. Saperika (1934) investigated the effect of Rivanol on the uterus and showed that it stimulated myometrical contractions in weak concentrations. In vivo there was a stimulating effect on both pregnant and non-pregnant cat myometrium with a dose of 2 mg/kg. Klingenberg et al. (1961) showed that protamine and acridine caused isolated strips of

guinea pig uterus to contract. These early observations suggested that the use of extra-amniotic injections of acridine dyes to induce abortion depended on a true oxytocic effect rather than mechanical distension and separation of chorion from decidua.

Manabe (1962) suggested that extra-ovular injections of Rivanol causes mechanical stimulation of the uterus. Extensive detachment of the membrane and the stimulation of the uterus caused by Rivanol in extra-ovular space can precipitate labour. The catheter left in situ also was thought to stimulate the uterine contractions. Mechanical stimulation can also cause reflex release of oxytocin.

Gustavi (1974) suggested that extra-ovular procedures (including injections of Rivanol) act by releasing lysosomal hydrolytic enzymes within decidual cells. The enzymes released are thought to cleave prostaglandin precursor from membrane phospholipids and thereby provide substrate for prostaglandin synthesis.

It seems probable that the observed damage to decidual lysosomes is followed by the synthesis and release of prostaglandins resulting in uterine contractions and finally in abortion.

FRONTIERS IN RESEARCH

The search for a safer solution for extra-amniotic injection for termination in the 2nd trimester has led to the discovery of many substances. Cohen in 1846 first described the extra-ovular injections of Rivanol for termination of pregnancy in second trimester. Kashiwara and Fujibayashi of Japan (1952) described the technique of injection of rivanol by catheter in the extra-ovular space.

Manabe from Japan (1969) used Rivanol along with oxytocin injections. Instillation abortion interval varied between 19 hours to 33 hours.

Lewis et al. (1971) described the oxytocic effect of the acridine dyes and their use in termination of mid-trimester pregnancy. All the patients aborted after a mean induction-delivery interval of 59 hours.

Carl-Axel-Ingemanson of Sweden (1973) compared the results of Rivanol with extra-amniotic injection of hypertonic saline. A higher percentage of successful abortions was obtained in the Rivanol-catheter group than with saline group.

Anjaneyulv (1977) used ethacredine lactate as extra amniotic injection and unitocin (spartine sulphate) 150 mg 1/m one hourly

for 3 doses were given to assist the expulsion. The average successful rate within 72 hours was 81.4%.

Ananthakrishnan et al. (1978) used ethacridine lactate with 10 units pitocin extra-amniotically. He found average induction abortion interval of 28 hours 10 minute with net success rate of 73.3%. Sepsis was seen in one patient who came for follow up after 10 days.

Karne et al. (1980) performed a comparative study of 392 mid-trimester abortions with intra-uterine injection of normal saline, 20% saline, prostaglandins and ethacridine lactate. He found success rate of 96% in 48 hours in prostaglandin group; 90% in intra-amniotic, 20% saline group, 87.5% in emcredil with oxytocin infusion group and 80% in only emcredil group.

A comparative study of middle trimester abortion by serial intramuscular injections of 15-methyl prostaglandin $F_{2\alpha}$ and by extra-amniotic infusion of 0.1% ethacridine lactate has been carried out by Mrs. R. Sofat (1984). Success rate in prostaglandin group was 100% and induction abortion interval was 14.23 hours.

Anirudh Malpani et al. (1986) did a comparative study of 2 prostaglandin analogues (Carboprost and sulprostone) with

ethacridine lactate for second trimester abortion. It was observed that the induction abortion interval was significantly shorter with carboprost. It was 20 hours 10 min. with sulprostone group and 14 hours 20 min. with carboprost group.

The Indian Council of Medical Research found a success rate of 78.1% in a series of over 1500 mid-trimester abortions with 1 mg of extra-amniotic 15(S)-15 Methyl PG $F_{2\alpha}$.

Karim and Sharma (1988b) used single injections of 25 mg of PGF $_{2\alpha}$ extra-amniotically to terminate second trimester pregnancies. The extra-amniotic administrations of 15 Me-PGF $_{2\alpha}$ appears to be a more desirable route of administration than repeated intra-muscular injections which produce unacceptable level of gastro-intestinal side effects.

Kher R.A., Ingle M.K. et al. conducted a trial at NWM Hospital using ethacridine lactate and extra-amniotic single dose of 15(S)-15 Methyl PGF $_{2\alpha}$ to perform second trimester medical termination of pregnancy and the results were compared with those of ethacridine lactate used with oxytocin augmentation. It was found that the success rate and incidence of complete abortion was higher with ethacridine + carboprost combination.

J.N. Martin, M. Bygdeman, A. Leader and N. Wigvist performed early second trimester abortions using extra-amniotic instillations of Rivanol solution and a single injection of $\text{PGF}_{2\alpha}$ and found a successful induction-abortion after 18 hours 20 min. It was found that this method combines the immediate uterotonic effect of prostaglandin with the delayed oxytocic response to Rivanol.

Mid-trimester pregnancy termination by extra-ovular instillation of PG and PG analogues, Selected Studies

Author & Year	No. of Patients	Type of PG	Dose	Trial Period (hrs)	I.A. Interval	Success Rate (%)
Wigvist et al. (1972)	50	$\text{PGF}_{2\alpha}$	250-750 μg	30	24 hr 12 min	90
Aingorani & Ganesh (1972)	20	$\text{PGF}_{2\alpha}$	500 μg	30	19 hr	80
WHO Multicentric trials (1976)	660	15Me $\text{PGF}_{2\alpha}$	0.92 mg	36	-	83
ICMR Multicentric trials (1988)	1569	15Me $\text{PGF}_{2\alpha}$	1 mg	36	14.8 hr	78

ANALYSIS OF COMPLICATIONS

The incidence and magnitude of the complications are detected by various factors, the foremost being the nature of the abortifacient agent. The other factors involved in modifying the results are the duration of pregnancy, parity and associated medical disorders.

1. HAEMORRHAGE

Haemorrhage is the commonest type of life threatening complication. Haemorrhage is not a problem in prostaglandin-induced abortions. $\text{PGF}_{2\alpha}$ was found superior to oxytocin in reducing excessive post-abortion bleeding in women at high risk of developing atonic postpartum haemorrhage (Nelson, 1980)

Ruoff et al. (Karuni, 1979) compared the amount of blood loss in both the groups and found that post-abortion blood loss was quite less in the PG group as compared to oxytocin. In a study of Rajan et al. (1980) by oxytocin augmentations there were seven fold increase in the incidence of haemorrhagic complications.

2. UTERINE ABNORMAL ACTIVITY

Prostaglandins induces uterine contractions at all stages of pregnancy. It causes an increase in oxytocin receptors on myometrium making it more sensitive to contractile action of oxytocin. Thus, the over stimulation of uterine myometrium can occur in any case or may fail to induce in some.

No case of uterine hypertonus was reported by Karim and Sharma (1971) and Craft and Yip (1978). Cervical injury was more

common with intra-amniotic than extra-amniotic procedures and was mainly seen in multipara women.

3. GASTRO-INTESTINAL EFFECTS

In isolated proportions longitudinal muscle of gut is contracted by $\text{PGF}_{2\alpha}$ while the circular muscle is relaxed. Hormone propulsion activity is enhanced in human and thus colic and diarrhoea are important side effects. PGs act directly on the intestinal mucosa and increase water content, electrolyte and mucus secretion. Episodes of vomiting and diarrhoea were frequent but not troublesome in majority of patients (Graft, 1972). Nausea, vomiting and diarrhoea were more frequently observed in multipara (Theiry and Amy, 1974).

Gastro-intestinal symptoms were the most common side effects with PG group as compared to oxytocin group (Hingorani et al., 1988).

4. COAGULOPATHY

Intravenous oxytocins were found to increase the risk of consumptive coagulopathy (Cohen and Ballard, 1974) as compared to prostaglandins. Oxytocin causes an increased release of thromboplastins into the maternal circulation and leads to coagulation abnormality.

In case of extra-ovular 0.1% Rivanol, and prostaglandins $E_{2\alpha}$; fibrinogen levels showed a slight increase after the instillations of the drug but euglobulin lysis time was normal throughout. The platelet count and prothrombin time showed no significant change; so by use of ethacridine + $PGF_{2\alpha}$ combination there is complete absence of haemorrhage complications.

5. CARDIOVASCULAR SYSTEM

Selective effect of prostaglandins on uterus without any side effect on cardiovascular system was reported by Karim (1971). Pulse, BP showed no changes during period of instillation (Craft Yip, 1972).

6. PROBLEMS IN SUBSEQUENT PREGNANCIES

Although it is not more than 20 years since the first abortion was carried out using prostaglandins, little information is available about the long term physical sequelae of pregnancy termination in the second trimester of pregnancy. Mackenzie and Fry (1988) assessed the subsequent fertility of 140 women whose pregnancies were terminated with prostaglandins in second trimester.

Reduced fertility after prostaglandin induced abortion was shown to be very infrequent.

Since abortion, 104 women in this series have conceived (97% within 24 months of abortion and five of them after some delay). Only one woman had not succeeded in achieving a desired pregnancy.

7. BODY TEMPERATURE

There is no evidence that prostaglandin used for abortion act as pyretic agent (Nelson and Bryans, 1979).

8. OTHERS

Fraser and Brash (1974) reported two cases of bronchospasm after prostaglandin instillation. Prostaglandin in the usual doses used for induction of abortion do not cause convulsions (Fraser and Gray, 1974).

Material and Methods

MATERIAL AND METHODS

The present study comprised of a comparative evaluation of efficacy of ethacridine-carboprost ($\text{PGF}_{2\alpha}$) combination to that of traditional ethacridine syntocinon combination. The study was conducted on 120 cases admitted to the Department of Obst. & Gynaec., M.L.B. Medical College & Hospital, Jhansi during the year 1993-1994.

The cases were divided into two groups as follows :

- (A) 60 patients for mid-trimester abortion where the method used was a combination of ethacridine and carboprost.
- (B) A similar number of cases where the method used was ethacridine plus syntocinon combination. These served as control.

The cases were further subdivided into three subgroups depending on the duration of gestation in weeks as shown in the table below :

TABLE I : SHOWING GROUPS AND DISTRIBUTION OF CASES ACCORDING TO GESTATIONAL AGE.

Group A	Emcredil + Carboprost	Total number of Cases
A ₁ (13-14 weeks)		4
A ₂ (15-17 weeks)		21
A ₃ (18-20 weeks)		35
	Total	60

Group B	Emcredil + Syntocinon	Total number of Cases
B ₁ (13-14 weeks)		7
B ₂ (15-17 weeks)		22
B ₃ (18-20 weeks)		31
	Total	60

SELECTION OF CASES

Women seeking medical termination of pregnancy between 13 and 20 weeks of gestation as calculated from the first day of last menstrual period were included in the study.

SELECTION CRITERIA

1. Weeks of pregnancy confirmed by estimation of the size of uterus and fundal height by bimanual pelvic abdominal examination.
2. All patients in the study gave informed consent prior to entering the trial.
3. Patients with known cardiac, pulmonary, renal or hepatic disease, epilepsy, suspected or known history of asthma were excluded from the study.
4. Patients with pelvic disproportion, a history of caesarian section or other major uterine surgery were not included.

5. Patients with active pelvic gynaecological infections were excluded.
6. Patients with uterine anomalies were not included.

The diagnosis of duration of pregnancy was made by :

- a. Per-abdominal or per-vaginal examination under aseptic condition.
- b. Ultrasonographic examination, if required.

All the patients of Group A (A_1 , A_2 and A_3) and Group B (B_1 , B_2 and B_3) of this study were subjected to the following laboratory investigations at the time of admission.

1. BLOOD for haemoglobin percentage, ABO-Rh; bleeding and clotting time if intra-uterine death is diagnosed.
2. URINE examination included the examination for albumin, sugar, microscopic examination and test for diagnosis of pregnancy; if needed.
3. Ultrasonographic examination in certain specific cases.

TREATMENT REGIMEN

1. All the patients were admitted to the hospital prior to treatment. Baseline clinical data and laboratory data, as well as administrative procedures were completed before treatment was started.

2. 150 ml of ethacridine lactate was instilled extra-aminotically through Foley's catheter no. 14 in all 120 patients. The catheter balloon was inflated with 10 cc of distilled water and hitched against the internal os of cervix.
3. In group A, 1 ml of (250 mg) inj. carboprost diluted in 10 cc of distilled water was instilled 6 hours after through the same catheter after clamping its distal end. While in rest 60 patients, I/V syntocinon-augmentation was done (Group B Control).
4. Two tablets of Lomotil (Diphenoxylate hydrochloride 2.5 mg and atropine sulphate 0.025 mg, Searle) and 1 tablet of Stemetil (prochlorperazine 5 mg, May and Becker) was given; if vomiting occurred with extra-aminotic carboprost.

METHODS

GROUP A

Ethacridine lactate is supplied in the form of 100 ml 0.1 % solution (2 x 100 ml) with brand name Icocredil made available by IVES Drugs (India) Pvt. Ltd. while CARBOPROST TROMETHAMINE ($\text{PGF}_{2\alpha}$) is supplied in the form of Inj. PROSTODIN made available by ASTRA-IDL LTD., Bangalore. Each ml. contains carboprost tromethamine equivalent to 250 mcg of carboprost. Prostodin is

presented in a package of 2 x 1 ml ampoules costing Rs. 107.18.

The solution is sterile and is refrigerated at 2-4 °C.

GROUP B

INTRAVENOUS OXYTOCIN

In the control group (Group B); Intravenous oxytocin was used 6 hours after ethacridine instillation in the form of oxytocin-drip starting with 0.5 unit syntocinon in 500 ml of 5% Dextrose at drip rate of 10 drops per minute to be increased to 30 units according to uterine contractions.

PARAMETERS TO BE ASSESSED

Monitoring of patient was done for pulse, blood pressure, temperature, any evidence of nausea, vomiting, diarrhoea, flushing, onset of contractions, induction-abortion interval, post-abortion blood loss. Completion of abortion was noted during the process of expulsion.

CRITERIA FOR SUCCESSFUL ABORTION

1. Induction-abortion interval not more than 72 hours.
2. Abortion without use of any additional method.
3. Not jeopardizing the reproductive capability of uterus.

Observations

OBSERVATIONS

In the present study, 120 cases admitted to the Department of Obstetrics and Gynaecology, M.L.B. Medical College, Jhansi, during the year 1993-94 were studied. Out of 120, 60 cases were placed in Group A and 60 cases in Group B.

AGE

Patients of all age groups were included in this study. The youngest patient was of 14 years and the oldest was of 42 years of age. Table I shows the age distribution of the 120 cases for the study.

TABLE I : SHOWING THE AGE DISTRIBUTION IN YEARS OF 120 PATIENTS

Age in years	No. of Cases	Percentage
10 - 15	01	0.83%
16 - 25	67	55.80%
26 - 35	46	38.30%
36 - 45	6	5.00%

Table I shows that the maximum number of cases 67 (55.8%) were in age group 16-25 years and only 1 (0.83%) was in the age group 10-15 years.

GRAVIDITY DISTRIBUTION

In our study most of the patients were primigravida. Table II shows the gravidity distribution.

Distribution of Cases According To Maternal Age

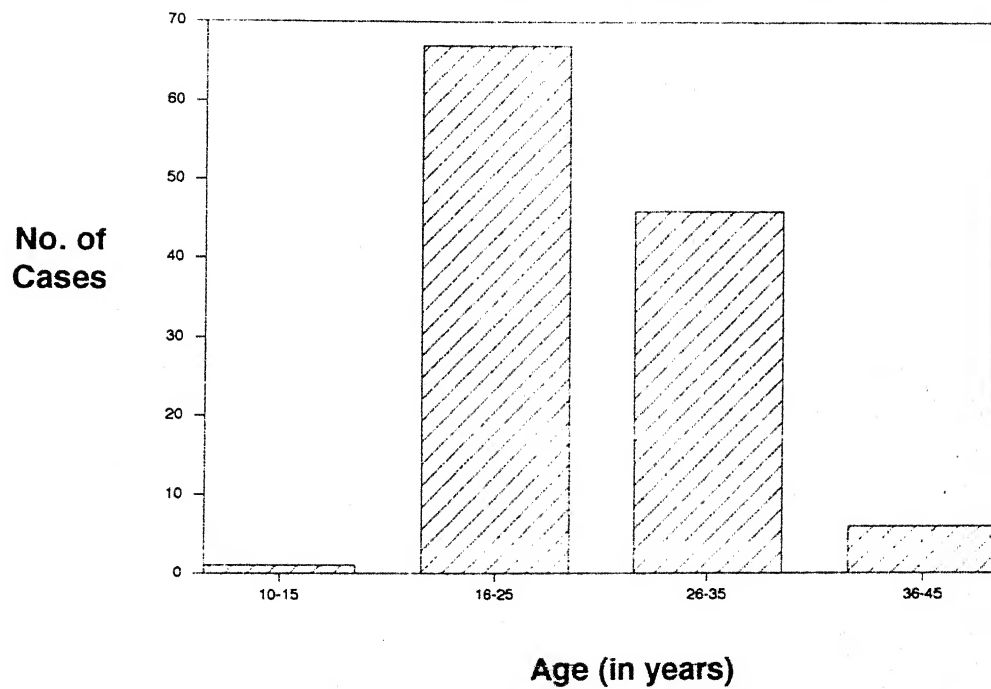


TABLE II : SHOWING THE GRAVIDITY DISTRIBUTION

Gravida	Number of Cases	Percentage
Gravida Ist	35	29.1%
Gravida IInd	11	9.1%
Gravida IIIrd	29	24.2%
Gravida IVth	26	21.6%
Gravida Vth & more	19	15.8%

Table II indicates that about 29.1% of the cases were in the primigravida group while 24.2% were third gravidas. Highest gravida in the series was 9th gravida.

MARITAL STATUS

Most of the patients were primigravida (unmarried) with illegitimate pregnancy.

The various indications for which pregnancy was terminated were :

- (i) Illegitimate Pregnancy
- (ii) As a birth spacing measure
- (iii) After sex determination
- (iv) Along with tubectomy.

PERIOD OF GESTATION

Gestation varied from 13-20 weeks in both the groups. Maximum number of cases were seen during 18-20 weeks of gestation while minimum in 13-14 weeks.

TABLE III : SHOWING DISTRIBUTION OF CASES ACCORDING TO PERIOD OF GESTATION IN WEEKS

Duration of Gestation (in weeks)	Number of Cases	Percentage
13 - 14 weeks	11	9.1%
15 - 17 weeks	37	30.9%
18 - 20 weeks	72	60.0%

DISTRIBUTION OF CASES

TABLE IV : SHOWING DISTRIBUTION OF CASES ACCORDING TO SOCIO-ECONOMIC STATUS (ICMR)

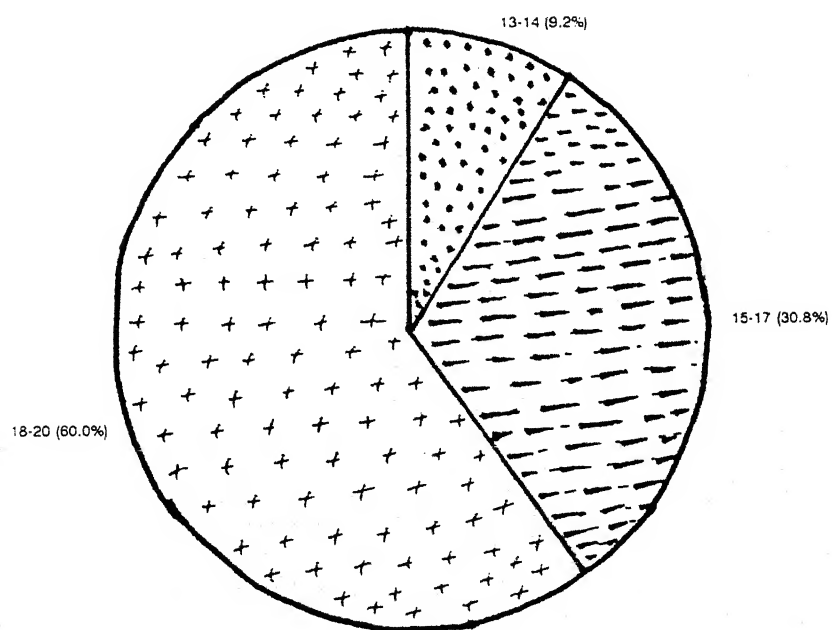
Socio-economic Status	Number of Cases	Percentage
High	4	3.4%
Middle	39	32.5%
Low	77	64.1%

It was found that out of a total of 120 patients, 4 (3.4%) belonged to high socio-economic status, 39 (32.5%) to middle socio-economic status while 77 (64.1%) cases were of low socio-economic status i.e. mid-trimester abortions are relatively common in low socio-economic status due to illiteracy, poverty and unawareness.

INSTILLATION-ABORTION INTERVAL

Patients were divided into two groups and the mean instillation-abortion interval compared.

Distribution of Cases According To Gestation Period



13-14 Weeks



15-17 Weeks



18-20 Weeks

TABLE V : SHOWING INSTILLATION-ABORTION INTERVAL

Group	24 hrs.	48 hrs.	72 hrs.	>72 hrs.	Mean instillation-abortion interval	
					Range	Mean
Group A	47	12	1	-	11 hrs. 20 min. to 49 hrs. 10 min.	18 hrs. 20 min.
Group B	19	33	6	2	14 hrs. to 72 hrs. 40 min.	32 hrs. 10 min.

Table V shows that in Group A 47 (78.3%) aborted within 24 hours; 12 (20%) within next 24 hours and 1 (1.66%) within 48 to 72 hours. No patient took more than 72 hours to abort.

In Group B, 19 (31.5%) patients aborted within 24 hours; 33 (55%) within 24 to 48 hours and 6 (10%) within 48 to 72 hours. 2 patients took more than 72 hours to abort.

TABLE VA : INSTILLATION-ABORTION INTERVAL IN RELATION TO DURATION OF PREGNANCY

Duration of Pregnancy	No. of Cases	Instillation-abortion Interval	
		Group A	Group B
13 - 14	11	28 hrs. 10 min.	34 hrs. 00 min.
15 - 17	37	22 hrs. 30 min.	30 hrs. 10 min.
18 - 20	72	16 hrs. 00 min.	24 hrs. 40 min.

Table VA shows that instillation-abortion interval was shorter in pregnancy between 18-20 weeks as compared to pregnancy of 13-14 weeks.

TABLE VB : INSTILLATION-ABORTION INTERVAL IN RELATION TO PARITY

Parity	Number of Cases	Instillation-abortion Interval	
		Group A	Group B
Nulliparous	34	20 hrs. 10 min.	26 hrs. 00 min.
Parous	86	18 hrs. 20 min.	32 hrs. 40 min.

MEAN INDUCTION TIME

Average interval was 18 hours 20 minutes in Group A (Emcredil + Carboprost) while it was 32 hours 10 minutes in Group B (Emcredil + I/V Oxytocin).

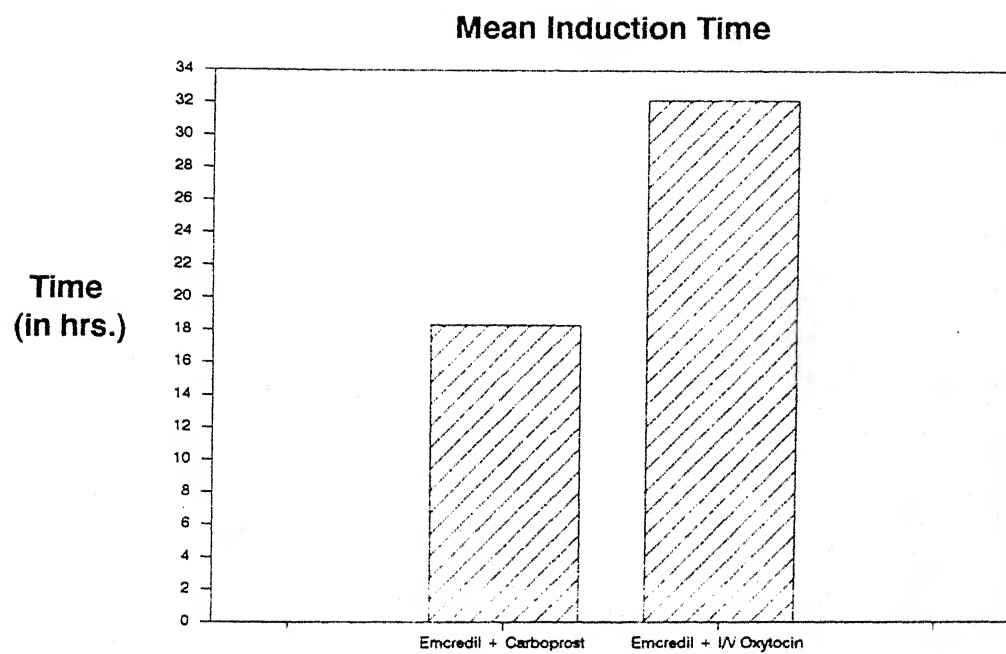
SUCCESS RATE

By "Successful" is meant those cases in which abortion was achieved within 72 hours. Table VI shows the success rate.

TABLE VI : SHOWING SUCCESS RATE

Group	Number of Cases	Successful abortion Number of Cases	Success Rate Percentage
Group A	60	60	100.00%
Group B	60	58	96.60%

Table VI shows that in our study 100% patients aborted within 72 hours in Group A while 96.6% patients aborted in Group B within 72 hours.



COMPLETENESS OF ABORTION

54 (90%) patients aborted completely when I/V oxytocin was augmented with emcredil instillation in contrast to 52(83.3%) patients in emcredil + carboprost group.

TABLE VII : SHOWING COMPLETENESS OF ABORTION

Group	Number of Cases	Complete	Incomplete
Group A	60	52	8
Group B	60	54	6

FAILURE OF PROCEDURE

There was not a single case of failure when carboprost was added to emcredil. Table VIII shows the failure rate.

TABLE VIII : SHOWING FAILURE RATE

Group	Number of Cases	Failure	Failure Rate
Group A	60	-	-
Group B	60	2	3.3%

As shown in Table VIII, failure rate was 0% in group A and 3.3% in group B. Failure was considered when abortion did not occur within 72 hours of instillation in whole trial.

Hysterotomy was done for both the failure cases in Group B.

COMPLICATIONS

TABLE IX : SHOWING THE COMPLICATIONS

Side effects	Group A		Group B	
	No. of Cases	Percentage	No. of Cases	Percentage
MINOR				
Nausea, Vomiting	3	5.0%	1	1.6%
Diarrhoea	1	1.6%	-	-
Headache, giddiness	-	-	2	3.3%
MAJOR				
Hypertonus	-	-	2	3.3%
Incoordinate uterine action	-	-	1	1.6%
Postpartum Haemorrhage	-	-	-	-
Rupture Uterus	1	1.6%	-	-

Gastro-intestinal symptoms were most common side effect with emcredil + carboprost combination which was experienced in 4 patients as compared to 1 patient in syntocinon group.

Nausea and vomiting were controlled with Inj. Stemetil and diarrhoea reported in 1 patient was controlled with Tab. Lomotil.

No case of uterine hypertonus and incoordinate action was reported in Group A as compared to 2 cases in Group B. Silent uterine rupture was noted during tubectomy in 1 case in Group A in which additional I/V Syntocinon was used due to patient's incomppliance. 2 patients in Group B needed hysterotomy for termination.

Discussion

DISCUSSION

If the single most important criteria for selecting a technique for second trimester MTP is its safety, Ethacridine scores above all the other methods. Its other advantages are - ease of procedure, single time procedure, low cost, no medical contra-indications and antiseptic properties. But the major disadvantages are prolonged induction - abortion interval and higher failure rate. In order to overcome these disadvantages, a combination of ethacridine with prostaglandins was proposed. This is with the idea of synergism of the latter with endogenous prostaglandins released by ethacridine.

Prostaglandins, because of their potent uterotonic action at all times of gestation, have been extensively used both to induce first and second trimester abortions as well as for induction of labour. The extra amniotic route of prostaglandins has special advantage over intra-muscular route in reducing the systemic side effects e.g. vomiting, diarrhoea and also avoiding serious complications of cervicovaginal injuries. The freedom from cervical injuries may be due to cervical ripening by endogenous prostaglandin released from decidua and metreurymeter like effect of the Foley's-balloon. The single extra-amniotic dose of

carboprost reduces its systemic side effects; the cost and inconvenience to the patients.

In the present study the PG analogue used was 15-methyl $F_{2\alpha}$ which is stable and does not produce pyrexia, rarely causes chilling and has a higher success rate.

In this study, a total number of 120 cases of mid trimester pregnancies were taken for abortion. In 60 cases, abortion was performed by extra-amniotic instillation of emcredil along with single injection of carboprost while in rest of the cases, augmentation was done with I/V infusion of syntocion drip 6 hours after emcredil instillation. All the cases were taken from the out patient department of Obst. and Gynae., MLB Medical College, Jhansi.

Maximum number of cases i.e. 67 (55.8%) were observed in age group of 16-25 years (Table I) followed by 46 (38.3%) in age group of 26-35 years. Only one (0.83%) was in the group of 10-15 years of age, while 6 (5.0%) were found to be in the age group of 36-45 years; the oldest patient being 42 years of age. These findings resemble with those reported in the literature (Nabriski et al., 1977) Bhosale et al. (1987) observed that 58.24% patients belonged to age group of 16-20 years.

Out of 120 cases studied, there were 35 (29.1%) primi-gravida and 29 (24.2%) third gravida (Table III). When compared with the studies by Kama et al. (1980) it was found that majority of patients who came for mid-trimester abortions in his study were third gravidas (32.6%).

A higher incidence of primi-gravidas in our study had illegitimate pregnancy. These observations could be due to poverty and illiteracy and lack of awareness in this region. The induction abortion interval was found to be less in multiparous women in Group A as compared to Group B (Table VB). Multiparous women had a lower incidence of incomplete abortions.

The reduced induction abortion interval observed in our study in Group A can be explained by hypothesizing that ethacridine lactate has a cervical priming effect. This effect is probably due to release of endogenous prostaglandins from the decidua which ethacridine induces. This primary action is best observed 6 hours after ethacridine instillation and permits optimal synergism between the cervical ripening effect of ethacridine lactate and the uterine contractility induced by the prostaglandin analogue. This ensures a decreased induction abortion interval and a decreased risk of uterine hypertonus in

second trimester abortions. Studies by Kher R.A., Ingle M.K. et al. have also revealed similar type of results.

In the present series, maximum number of cases [72 (60.0%)] were seen during 18-20 weeks of gestation while minimum number [11 (9.1%)] were seen during 13-14 weeks of gestation. This is mainly due to unawareness in primi-gravidas and lack of decision making in multi-gravidas (Table III). It was also found that out of a total of 120 patients, 77 patients (64.1%) belonged to low socio-economic status while 39 (32.5%) were in middle socio-economic groups (Table IV) indicating the fact that increased mid-tri abortions in low socio economic status were mainly due to illiteracy. These findings were similar to the results obtained by other researchers (N. Wilquist, 1986) who reported that about 68.4% patients in his study belonged to low socio-economic status.

Extra-amniotic instillation of emeredil with carboprost has significantly shortened the induction abortion interval in the present series. Majority of patients [47 (78.3%)] aborted within 24 hours in group A while 19 (31.5%) patients aborted within 24 hours in group B (Table V). Overall success rate was 100% in group A as compared to 96.6% in group B (Table VI).

Cases were considered successful when abortions were achieved within 72 hours. Average induction-abortion interval was 18 hrs 20 min. with the use of ethacridine-carboprost combination while it was 32 hrs 10 min. with ethacridine-syntocinon combination (Table V). There was statistically significant difference in the mean induction abortion interval. ($p < .01$)

These results are compared with those obtained by other workers. A study by Kher A.R. and Daftary N. showed a success rate of 93.2% in ethacridine-carboprost group with average induction abortion interval of 18 hrs 30 min.

In our study quite encouraging results were achieved. Only 2 patient failed to abort within 72 hours in group B where hysterotomy was performed. There was not a single case of failure when carboprost was used in combination with ethacridine.

No serious complications were encountered in both the groups except in one case of group A, where after abortion silent uterine rupture with broad ligament haematoma was discovered during tubectomy. This was mainly due to patients incomppliance whereby intravenous sympocinon was used along with this method which accelerated the effect of carboprost resulting in silent rupture.

Gastro-intestinal symptoms were observed in 4 cases in group A which were treated accordingly (Table IX).

Pyrexia was not much of the observed problem. There was only slight rise of temperature upto 38°C which settled on its own within 6-8 hours without any therapy. Total incidence was 5.1% and it was almost same in both the groups. Similar results have been reported by other workers (J.N. Martuni and M. Bygdeman, 1989), who observed incidence of pyrexia to be 7.4% with emcredil-carboprost combination.

Incidence of incomplete abortion was 13.3% in group A while it was only 10% in group B. Digital removal of retained placental pieces was done in most of the cases but in a few cases, surgical evacuation under I/V syntocinon infusion was needed. A study by Kher, A.R. had shown an incidence of incomplete abortion as 16.8%.

No case of cervical or perineal tear was observed in the present study. Karim and Sharma had reported a single case of cervical tear in their study in 1988 which was stitched and later patient made an ineventful recovery.

The patient's acceptance of this procedure was excellent; the side effects were less with extra-amniotic route and they were outweighed by the rapid abortion time, mild contractions and ease of administration. The low cost and minimum inconvenience makes this a promising procedure for second-trimester abortions.

Summary and Conclusion

SUMMARY AND CONCLUSIONS

The induction of early second trimester abortion by the extra-amniotic instillation of a single dose of prostaglandin $\text{PGF}_{2\alpha}$ with a solution of 0.1% ethacridine, an acridine derivative with antiseptic properties, seems to be a simple, efficacious and harmless procedure. This modification of the extra-amniotic abortion method combines these immediate uterotonic effect of prostaglandin with the delayed oxytocic response to Ethacridine.

Ethacridine lactate administered extra-amniotically in combination with $\text{PGF}_{2\alpha}$ acts in following ways to produce abortion:

- (a) Causes mechanical stripping of the entire sac from the uterine wall.
- (b) Ethacridine causes a stimulation of increased $\text{PGF}_{2\alpha}$ release from the decidua.
- (c) The catheter left in situ aids in mechanical stimulation of the uterus.
- (d) Prostaglandins acts indirectly through the release of oxytocin and appear to induce abortion primarily through uterine contractions.

(e) The combination of $\text{PGF}_{2\alpha}$ with Ethacridine effects an immediate increase in uterine contractility.

The present study was conducted with a view to shorten the instillation abortion interval and to assess the success rate and completeness of abortion.

Our observations have been discussed under the light of modern literature.

This study included 120 cases aged between 14 to 45 years and from primi-gravida to ninth gravida. Most of the patients were primi-gravida and usually with illegitimate pregnancy. All the patients were divided into two groups.

Group A : 60 patients where the method used for mid-trimester abortion was a combination of ethacridine and carboprost ($\text{PGF}_{2\alpha}$).

Group B : 60 cases where the method used was ethacridine plus I/V syntocinon augmentations which served as control.

Instillation abortion interval was (18 hrs 20 min.) less in group A than in group B (32 hrs 10 min.). Most of the patients in group A aborted within 48 hours.

By addition of Inj. carboprost to emcredil; 100% patients aborted within 72 hours while the success rate was 96.6% with emcredil-syntocinon.

No major complication was observed in group A except for some minor complications like gastro-intestinal symptoms which was experienced in 4 patients. No case of uterine hypertonus and incoordinate action was reported in group A as compared to 2 cases in group B. Silent uterine rupture with broad-ligament haematoma was noticed in 1 case in group A during tubectomy.

The following conclusions were drawn :

- (1) The technique is simple, cheap, safe and physiologically effective. No cervical dilatation was required even in unmarried patients, there was no difficulty in passing the catheters.
- (2) There is no danger of bladder or intestinal injury.
- (3) 0.1% solution has wide range of safety. Its potent and widespread bactericidal properties minimise the danger of pervaginal infection after extra-ovular injection. Infection was not seen in any of the case.
- (4) The extra-amniotic route of prostaglandins has special advantage over intra-muscular route in reducing the systemic

side-effects e.g. vomiting, diarrhoea and also avoiding serious complications of cervico-vaginal injuries. The freedom from cervical injuries is due to cervical ripening by ethacridine.

The single extra-amniotic dose of carboprost reduces its systemic side effects, the cost and inconvenience to the patients.

From this study we can therefore conclude that combination of extra-amniotic instillation of 150 cc of ethacridine lactate followed six hours later by single extra-amniotic instillation of 250 µg of 15(S), 15-methyl PGF_{2α} diluted to 10 ml with distilled water, can be considered as a method of choice for second trimester abortion.

This modification of the extra-amniotic method has other advantages for clinical application - the procedure is simple; economical, side effects are acceptable inadvertent intravascular injection is harmless and the possibility of infection is reduced. On the basis of our experience we conclude that this method is sufficiently promising for early second trimester abortions.

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MASTER CHART - I
EMCREDIL + CARBOPROST

Case No.	Name	Age (Yrs.)	Parity	S.E. Status	Marital Status	Duration of Gestation (Weeks)	I.A. Interval Hr. Min		C/I
1.	Kapori.	22	G ₃ P ₂ A ₀	Low	M	18-20	17	20	C
2.	Meena	18	G ₁ P ₀ A ₀	Low	U	18-20	14	10	C
3.	Kastori	36	G ₅ P ₄ A ₀	Low	M	16	46	20	I
4.	Swarna	20	G ₂ P ₁ A ₀	Mid	M	14	24	10	C
5.	Premvati	23	G ₃ P ₂ A ₀	Mid	M	16	22	20	C
6.	Reetu	26	G ₃ P ₂ A ₀	Low	M	18	18	00	C
7.	Noorjahan	30	G ₅ P ₃ A ₁	Low	M	18	20	10	C
8.	Phoolwati	32	G ₅ P ₄ A ₀	Low	M	16	28	10	C
9.	Guddoo	14	G ₁ P ₀ A ₀	Low	U	18	22	20	C
10.	Sundari	22	G ₂ P ₁ A ₀	Mid	M	14	32	10	I
11.	Ladkawar	34	G ₂ P ₁ A ₀	Low	M	16	34	00	C
12.	Alka	35	G ₃ P ₂ A ₀	High	M	18	16	40	C
13.	Suriya	30	G ₃ P ₂ A ₀	Low	M	18	24	30	C
14.	Radha	30	G ₄ P ₂ A ₁	Low	M	16	19	00	C
15.	Murti	18	G ₁ P ₀ A ₀	Low	U	16	49	10	I
16.	Laxmi	22	G ₂ P ₁ A ₀	Low	M	18	40	20	C
17.	Anisha	34	G ₁ P ₀ A ₀	Mid	M	20	19	30	C
18.	Betibai	40	G ₆ P ₅ A ₀	Low	M	18-20	38	20	C*
19.	Angoori	38	G ₄ P ₃ A ₀	Low	M	20	22	10	C
20.	Usha	26	G ₃ P ₂ A ₁	Low	M	20	25	00	I
21.	Maya	35	G ₃ P ₂ A ₀	Low	M	18	20	40	C
22.	Sunita	35	G ₂ P ₁ A ₀	Mid	M	16	18	30	I
23.	Pushpa	36	G ₃ P ₂ A ₀	Mid	M	14	22	00	C
24.	Laxmi	24	G ₃ P ₁ A ₁	Low	M	14	29	10	C
25.	Meera	23	G ₄ P ₃ A ₀	Low	M	16	14	30	C
26.	Rammoorti	21	G ₂ P ₁ A ₀	Low	M	18	11	20	C
27.	Savitri	22	G ₃ P ₂ A ₀	Low	M	18	16	20	C
28.	Pista	34	G ₂ P ₈ A ₀	Low	M	20	18	50	C
29.	Laxmi	35	G ₅ P ₄ A ₀	Low	M	20	20	10	I
30.	Umarjahan	19	G ₁ P ₀ A ₀	Mid	U	18	13	40	C

Contd...

31.	Sukhdevi	24	G ₃ P ₀ A ₀	Low	M	18	18	10	C
32.	Munni	42	G ₆ P ₂ A ₁	Low	M	16	26	00	C
33.	Harkumari	25	G ₃ P ₄ A ₀	Mid	M	18	22	20	C
34.	Kamlesh	22	G ₄ P ₂ A ₁	Mid	M	18	14	10	C
35.	Anita	18	G ₁ P ₂ A ₀	Low	U	20	28	40	C
36.	Mumtaz	20	G ₁ P ₀ A ₀	Mid	U	20	19	20	C
37.	Sunita	22	G ₂ P ₀ A ₀	Low	M	18	20	10	C
38.	Anita	22	G ₁ P ₁ A ₀	Mid	U	14	16	20	I
39.	Mandevi	25	G ₃ P ₀ A ₀	Mid	M	16	17	00	C
40.	Urmila	26	G ₅ P ₂ A ₁	Low	M	18	16	20	C
41.	Pushpa	28	G ₄ P ₃ A ₀	Mid	M	18	29	40	I
42.	Kusum	29	G ₅ P ₃ A ₂	Mid	M	20	22	10	C
43.	Savitri	31	G ₇ P ₂ A ₀	Low	M	20	14	30	C
44.	Rani	19	G ₁ P ₆ A ₀	Low	U	16	20	10	C
45.	Abhilasha	21	G ₂ P ₀ A ₀	High	M	18	24	20	C
46.	Uma	21	G ₂ P ₁ A ₀	Mid	M	18	19	40	C
47.	Kamla	22	G ₁ P ₁ A ₀	Low	U	16	26	10	C
48.	Kavita	25	G ₃ P ₀ A ₀	Low	M	20	13	20	C
49.	Savitri	24	G ₄ P ₂ A ₁	Low	M	20	21	00	C
50.	Suman	24	G ₄ P ₂ A ₀	Mid	M	16	24	40	I
51.	Guddi	26	G ₃ P ₃ A ₀	Mid	M	16	20	40	C
52.	Anisha	20	G ₁ P ₀ A ₀	Mid	U	18	16	30	C
53.	Kiran	19	G ₁ P ₀ A ₀	Low	U	16	25	20	C
54.	Ramkumari	20	G ₂ P ₁ A ₀	Mid	M	20	21	40	C
55.	Preeti	23	G ₃ P ₂ A ₀	Low	M	20	26	20	C
56.	Baby	21	G ₂ P ₀ A ₁	Low	M	18	36	00	C
57.	Usha	22	G ₂ P ₁ A ₀	Low	M	16	32	40	C
58.	Meera	25	G ₄ P ₃ A ₀	Mid	M	16	30	20	C
59.	Kapoori	29	G ₆ P ₅ A ₀	Low	M	14	16	00	C
60.	Taxmi	33	G ₄ P ₃ A ₀	Low	M	18	20	10	C

* - Silent Rupture of Uterus

C - Complete I - Incomplete M - Married U - Unmarried

MASTER CHART - II
EMCREDIL + INTRAVENOUS OXYTOCIN

Case No.	Name	Age (Yrs.)	Parity	S.E. Status	Marital Status	Duration of Gestation (Weeks)	I.A. Interval Hr. Min		C/T
1.	Manju	19	G ₁ P ₀ A ₀	Low	U	18	22	40	C
2.	Rani	22	G ₂ P ₁ A ₀	Low	M	18	40	20	C
3.	Santosh	20	G ₃ P ₂ A ₀	Low	M	14	33	10	C
4.	Usha	24	G ₅ P ₃ A ₁	Low	M	20	56	20	C
5.	Nisha	28	G ₃ P ₂ A ₀	Mid	M	18	30	40	I
6.	Sandhya	36	G ₆ P ₃ A ₂	Mid	M	14	36	20	C
7.	Malti	40	G ₈ P ₄ A ₁	Low	M	18	14	10	C
8.	Sunita	20	G ₁ P ₀ A ₀	Low	U	18	38	00	C
9.	Alka	18	G ₁ P ₀ A ₀	High	M	18	42	20	C
10.	Ramkumari	18	G ₁ P ₀ A ₀	Low	U	20	30	40	C
11.	Sadhana	21	G ₂ P ₁ A ₀	Low	M	16	31	00	C
12.	Afsana	18	G ₁ P ₀ A ₀	Low	U	20	24	20	C
13.	Munni	24	G ₃ P ₂ A ₀	Low	M	16	39	10	T
14.	Anju	25	G ₅ P ₃ A ₁	Low	M	16	56	20	C
15.	Meena	20	G ₂ P ₁ A ₀	Low	M	18	38	00	C
16.	Rajni	21	G ₃ P ₂ A ₀	Mid	M	14	32	10	C
17.	Geeta Rani	26	G ₄ P ₃ A ₀	Low	M	18	30	10	C
18.	Rekha	25	G ₂ P ₁ A ₀	Mid	M	20	19	55	C
19.	Mamta	25	G ₄ P ₃ A ₀	Low	M	14	30	40	C
20.	Malti	30	G ₅ P ₃ A ₁	Low	M	20	44	10	I
21.	Saroj	29	G ₆ P ₅ A ₀	Low	M	18	72	40	**
22.	Manju	21	G ₁ P ₀ A ₀	Low	U	20	32	05	C
23.	Phoolo	21	G ₂ P ₁ A ₀	Low	M	16	24	00	C
24.	Sashi	20	G ₃ P ₂ A ₁	Mid	M	18	20	20	C
25.	Neelam	18	G ₁ P ₀ A ₀	Low	U	20	34	10	C
26.	Uma	19	G ₁ P ₀ A ₀	Low	U	18	48	20	C
27.	Usha	24	G ₃ P ₂ A ₀	Low	M	16	40	00	C
28.	Rani	23	G ₃ P ₂ A ₀	Low	M	20	33	25	C
29.	Parvati	28	G ₆ P ₂ A ₃	Low	M	15	40	50	T
30.	Bano	27	G ₅ P ₄ A ₀	Low	M	18	24	10	C

Contd...

31.	Kusum	36	G ₆ P ₅ A ₀	Low	M	20	26	10	C
32.	Prembala	32	G ₄ P ₃ A ₀	Low	M	18	29	00	C
33.	Kamla	29	G ₄ P ₃ A ₀	Low	M	20	43	20	I
34.	Kaushalya	25	G ₃ P ₁ A ₁	Low	M	18	18	40	C
35.	Usha	24	G ₃ P ₂ A ₀	Mid	M	14	30	20	C
36.	Janki	24	G ₃ P ₂ A ₀	Low	M	16	33	10	C
37.	Prabha	20	G ₂ P ₁ A ₀	Low	M	16	28	40	C
38.	Munni	18	G ₁ P ₀ A ₀	Low	U	18	26	00	C
39.	Mayadevi	19	G ₁ P ₀ A ₀	Low	U	20	42	35	C
40.	Lala	25	G ₃ P ₂ A ₀	Low	M	18	22	05	C
41.	Asha	24	G ₂ P ₁ A ₀	Low	M	16	35	15	C
42.	Malti	24	G ₃ P ₂ A ₀	Low	M	20	37	40	C
43.	Rani	20	G ₁ P ₀ A ₀	Low	M	16	43	10	C
44.	Anju	30	G ₃ P ₂ A ₀	High	M	14	38	20	I
45.	Phoola	34	G ₅ P ₄ A ₀	Low	M	18	18	40	C
46.	Mamta	32	G ₃ P ₂ A ₀	Low	M	20	26	00	C
47.	Kamla	31	G ₆ P ₃ A ₁	Low	M	16	22	40	C
48.	Deva	27	G ₄ P ₃ A ₀	Low	M	18	26	55	C
49.	Meera	25	G ₄ P ₃ A ₀	Low	M	18	30	45	C
50.	Sangita	23	G ₃ P ₂ A ₀	Mid	M	14	78	10	**
51.	Noorjahan	21	G ₂ P ₁ A ₀	Low	M	18	58	20	C
52.	Maya	20	G ₁ P ₀ A ₀	Low	U	20	37	20	C
53.	Nisha	23	G ₃ P ₂ A ₀	Mid	M	18	33	40	C
54.	Rati	28	G ₄ P ₂ A ₁	Low	M	16	40	10	C
55.	Sunita	29	G ₄ P ₃ A ₀	Low	M	20	30	40	C
56.	Rampyari	22	G ₃ P ₂ A ₀	Low	M	18	35	10	C
57.	Kastoori	27	G ₁ P ₀ A ₀	Low	U	18	26	00	C
58.	Pushpa	24	G ₂ P ₁ A ₀	Low	M	14	29	10	C
59.	Daya	25	G ₃ P ₂ A ₀	Low	M	16	46	20	I
60.	Sukhrani	25	G ₄ P ₃ A ₀	Low	M	18	38	20	C

** Hysterotomy

C - Complete I - Incomplete M - Married U - Unmarried

WORKING-PERFORMA

"Clinical trial of ethacridine-Carboprost(PGF₁) combination
with ethacridine-syntocinon for mid-trimester abortions."

Case No.

MRD No.

Name

Ward/Bed No.

Age

Gravida/Parity

Address

Married/Unmarried

Duration of marriage

Educational status

Wife

Husband

Occupation

Wife

Husband

Monthly family income

No. of adults

No. of children

Socio-economic status- Poor/Lower middle class/Upper middle class/Rich

Religion

Habitation-Rural/Urban

DOA-

DOD-

Consultant-

Chief Complaints:

Duration

Ammenorrhoea-

Any associated c/o- vomiting/pain in abdomen/any evidence of PID.

Others-----

Menstrual History-

Age at Menarche-

Duration of menses in days-

Duration of cycles in days-

~~Amount~~
~~Duration~~ of loss-Average/Excessive/Scanty-

LMP-

EDD-

Obstetrics History-

- (a) Past pregnancies:

<u>No.</u>	<u>Date</u>	<u>Duration of preg.</u>	<u>Abnormality</u> <u>in preg.</u>	<u>Type of</u> <u>labour</u>	<u>Per-</u> <u>period</u>	<u>Child</u>
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- 1.
- 2.
- 3.

(b) Present preg.-

No. of antenatal checkup-

Reason for termination-

Alive/Dead. foetus-

Contraceptive History-

Contraceptive education- Yes/No

Contraceptive practice-

Dietetic History- Veg/Non-vegetarian

Past Medical history-

(a) During antenatal period.

(b) Preceding to that.

Drug History-sp. (H/O hypersensitivity to Prostaglandins)

(a) During antenatal period.

(b) Preceding to that.

Family History-

General examination:

G.C.-

Height-

P/R-

Temp.-

Anaemia-

Oedema-

wt.-

B.P.(mm.of Hg)-

H/L-

Jaundice-

Others-

Obstetrical Examination:

Breast & Nipples-

P/A-

FH-

EB-

P/V-

Investigations:

Blood-

Hb%

ABO-Rh-

BT

if IUD.

CT

albumin

Urine

Urine exam.

sugar

M/E.

Ultrasonography-

Observations: Date & Time of Institution of ethacridine-
Pd. of gestation in weeks-

0hr. 3hrs. 6hrs. 12hrs. 18hrs. 24hrs. 48hrs. 72hrs.

Type of

Drug

Amount/
conc.

Route of
adm.

P/R

B.P. (mmHg)

Temp.

N/V/D

Pain

Bleeding P/V

Contractions

P/V findings:

Dilatations

Condition
of Cervix

Station

Memb.

State of
catheter.

Time of expulsion of foetus-

Time of expulsion of placenta-

Induction- Abortion Interval-

Post-Abortal Complications:

Pain-

Post-Abortal bleeding-

Incomplete Abortion-

Post-Abortal Infection-

Genital-tract trauma-

Others-

Remarks-

Signature of Doctor-
